

Patent



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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re New Continued Prosecution Application:

) Prior Application:

Applicants: GOELET, Philip *et al.*

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) Examiner: ARTHUR, Lisa

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Application No.: 09/258,132

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) Group Art Unit: 1655

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Filing Date: 26 February 1999

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Title: "Nucleic Acid Typing By Polymerase  
Extension of Oligonucleotides Using  
Terminator Mixtures"

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5 August 2002

Commissioner for Patents  
Box CPA  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

SIR or MADAM:

Prior to calculation of the filing fee and examination on the merits, please amend the new continued prosecution ("CPA") identified above as follows:

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Notice Regarding Filing of Correspondence by  
"Express Mail" Pursuant to 37 CFR 1.10

"Express-Mail" mailing label number: EV 035772795 US  
Date of Deposit: 5 August 2002

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In the Claims:

Please add the following new claim 64.

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--64. (New) A method of determining the identity of one or more nucleotide bases at a plurality of specific positions in one or more nucleic acid molecules of interest, comprising:

cl (a) treating a sample comprising the one or more nucleic acid molecules of interest, if the nucleic acid molecules of interest comprise double-stranded nucleic acid, so as to obtain unpaired nucleotide bases spanning the specific positions, or directly employing a sample comprising the one or more nucleic acid molecules of interest in step (b) if the nucleic acid is single-stranded;

(b) contacting the sample from step (a) with a plurality of different oligonucleotide primers, wherein:

(i) each such oligonucleotide primer hybridizes, under high stringency hybridization conditions, to a corresponding different stretch of nucleotide bases present in the nucleic acid molecules of interest which is immediately adjacent to the specific position of a nucleotide base to be identified with that oligonucleotide primer, so as to form a duplex such that the nucleotide base to be identified is the first unpaired base of the nucleic acid molecule of interest immediately downstream of the 3' end of the oligonucleotide primer; and

(ii) each different oligonucleotide primer incorporates a corresponding different affinity moiety which permits polymerase extension of the oligonucleotide primer with terminators of a terminator reagent and permits affinity separation of the extended oligonucleotide primer from the terminator reagent;

(c) contacting the duplexes from step (b) with a terminator reagent free of dATP, dCTP, dGTP, and dTTP and comprising four different terminators of a nucleic acid template-dependent primer extension reaction, each terminator comprising a different detectable label corresponding to the terminator, wherein one of the terminators is complementary to a nucleotide base to be identified by each of a oligonucleotide primers, wherein the contacting is carried out in a primer-

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extension reaction medium under conditions sufficient to permit a template-dependent primer extension reaction which incorporates the complementary terminator onto the 3' end of each of the different oligonucleotide primers to thereby extend the 3' end of each of the oligonucleotide primers by one terminator;

(d) affinity separating the respective extended oligonucleotide primers from primer-extension reaction medium by causing each of the extended oligonucleotide primers to contact an affinity group attached to a solid support, such affinity group being complementary to the affinity moiety incorporated in the oligonucleotide primer; and

(e) determining the presence and identity of the nucleotide base at each of the respective specific positions in the one or more nucleic acid molecules of interest by detecting the detectable label of the terminator incorporated at the 3' end of each of the affinity separated extended oligonucleotide primers.

#### REMARKS

The present preliminary amendment is being filed simultaneously with a new continued prosecution application based on United States patent application Serial No. 09/258,132, filed on 26 February 1999 and having the title "Nucleic Acid Typing by Polymerase Extension of Oligonucleotides Using Terminator Mixtures" ("the parent '132 application").

An Office Action dated 16 May 2001 was issued in connection with the parent '132 application in which claims 60 through 63 inclusive of the application were finally rejected. The final rejection was appealed in a notice of appeal timely submitted to the United States Patent and Trademark Office on 16 November 2001 with a certificate of first class mailing. The appeal was dated 3 January 2002. A request to extend the time to file an appeal brief in the appeal with respect to the parent '132 application through 3 August 2002 is being submitted with the subject continued prosecution application. The continued prosecution application is being filed by Express Mail on

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5 August 2002, the first business day after 3 August 2002. Consequently, the subject continued prosecution application is being filed before abandonment of or termination of proceedings with respect to the parent '132 application, as required under 37 CFR 1.53(d)(ii).

New claim 64 is being added with the present preliminary amendment. New claim 64 finds support in the specification of the application as filed, for example, at page 27, lines 12 through 24; page 29, line 19 through page 30, line 3; and page 31, lines 23 through 35. It is submitted that new claim 64 does not constitute new matter.

In the Office Action of 16 May 2001, a prior rejection of claims 60 through 63 inclusive as unpatentable over claims 13 through 56 inclusive of United States patent No. 6,004,744 ("the '744 patent") under the judicially created doctrine of obviousness-type double patenting was maintained and made final. A rejection of claims 60 through 63 inclusive as unpatentable over claims 1 through 48 inclusive of United States patent No. 5,888,819 ("the '819 patent") under the doctrine of obviousness-type double patenting in view of a publication by Dattagupta et al. not identified further was also maintained and made final. To obviate the prior double-patenting rejections, a terminal disclaimer for the parent '132 application with respect to the '744 patent and the '819 patent had been submitted to the United States Patent and Trademark Office on 28 February 2001 along with a reply to an Office Action. In the Office Action of 16 May 2001, however, it was stated that no terminal disclaimer had been received. Accompanying the present preliminary amendment as Appendix A is a copy of the terminal disclaimer of 28 February 2001, together with a copy of a receipt-acknowledgement postcard bearing the stamp of the mailroom of the Patent and Trademark Office which indicates that the terminal disclaimer was received by the Patent and Trademark Office.

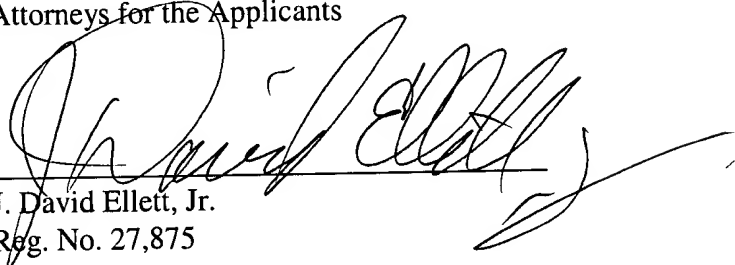
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Entry of the present preliminary amendment and the previously submitted terminal disclaimer is respectfully requested. Early allowance of the subject application is earnestly solicited.

Respectfully submitted,

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by

  
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